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EXAMINER	
JONES, HUGH M	
ART UNIT	**PAPER NUMBER**
2128	
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12/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,968	SUN ET AL.	
	Examiner	Art Unit	
	Hugh Jones	2128	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other. _____.

DETAILED ACTION

1. Claims 1-10 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 3 provides for the use of *patient specific data*, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

5. Claim 3 is also rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Interpretation

6. The following interpretations are noted: Claim 10: is directed to simultaneously depositing at different locations at the same exact time; Claims 5, 7-8 are process claims, not product-by-process claims; they are directed to intended use and therefore are provided no patentable weight; Claim 10: "for *simultaneously depositing specified hydrogels with different viscosities" refers to intended use* – no patentable weight. The

claims are directed to a multi-nozzle biopolymer deposition apparatus. "*thereby constructing a scaffold from the designed scaffold model*" also refers to intended use and is therefore provided no patentable weight.)

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-10 are rejected under 35 U.S.C. 102(e) as clearly anticipated by Boland et al. (US 7,051,654).

9. Boland discloses:

1. A process for manufacturing complex parts and devices comprising:

(a) utilizing a CAD environment to design a part or device to be created *and*
(b) converting the CAD designed part or device into a heterogeneous material and multi-part assembly model which can be used for multi-nozzle printing; and

Col. 14:

Using the techniques described above, it has been discovered that cells may be printed onto a substrate and remain viable. However, not only does the present invention provide a mechanism for ensuring cell survival, it also provides the ability to easily, quickly, and inexpensively manipulate the types of patterns, densities, etc., that may be printed. For instance, the printed patterns may be simple or complex, and have a shape that is regular or irregular. In fact, due to the control provided by the present invention, there is essentially no limit on the patterns or shapes capable of being printed according to the present invention.

Col. 15:

Regardless of the pattern and/or density selected, the present invention may utilize various control techniques to ensure that the desired results are achieved. Unlike conventional techniques for printing cells that involve contact-deposition, the present invention provides a precise, well-controlled method of printing that does not substantially risk contamination. The non-contact, ink-jet printing techniques employed in the present invention also allow for better control than previously realized when depositing viable cells onto a substrate. Generally speaking, any well-known ink-jet printing control technique may be utilized in the present invention. For instance, a printer driver may be used to control the movement of the printer head, the movement of the substrate, the voltage delivery to the printer head, etc. Some suitable ink-jet printing control techniques that may be adapted for use in the present invention are described in

Referring to FIG. 8, for instance, a block diagram of one embodiment of a control system that may be used in the present invention is shown. As shown, the system includes a host computer 500 and an ink-jet printer 100 (FIG. 1). In the host computer 500, the exchange of various data and control are generally performed between an OS (Operating System) 501 and application software 502 that operates on the OS 501. Print data is exchanged between the OS 501, the application software 502, and a printer driver 503, and is sent to the printer 110 through the printer driver 503. The present invention is by no means limited to any particular printer driver because, as is well known to those skilled in the art, numerous types of printer drivers may accomplish the same functions desired in the present invention.

The flow of data in the process of printing out cell composition(s) from the printer **100** is generally described below. Typically, a user first inputs the desired cell density and pattern into the application software **502**. These data signals are then sent to the printer driver **503**. The printer driver **503** performs processing for the received signals, and also generally converts them into binary signals. The printer driver **503** sends these signals to the interface, in the host computer **500**, which is used for the printer **100** or the interface for a file storage unit or the like. The signals are then sent as output to the interface for the printer **100**, and the data signals are sent to controller software **601** in the printer **100**. Matching between the set print mode and a printer head **110** is checked. Thereafter, the print data is transferred to engine software **602**. In this case, the engine software **602** interprets the received data as data indicating the print mode and the data structure designated by the controller software **601**, converts the print data into discharge pulses, and sends them to the printer head **110**. With this operation, cell composition(s) are discharged from the printer head **110**. The ID information of the printer head **110**, the ID information of each cell composition reservoir, etc., are sent to the engine software **602**. On the basis of these

(c) printing the designed part or device using multiple, different, specialized nozzles.

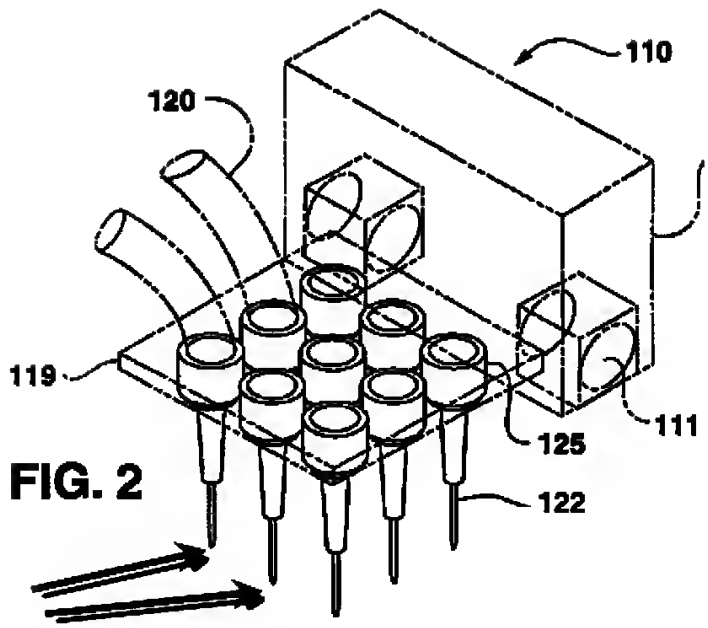


FIG. 2

Col. 4:

Generally speaking, any known ink-jet printer and/or ink-jet printing system may be incorporated for use in the present invention. Ink-jet printers are typically either "DOD" (Drop-On-Demand) or "continuous" ink-jet printers. In a continuous ink-jet printer, a stream of fluid con-

In addition, various ink-jet printers used to print layers on plastic parts (known as "rapid prototyping") may also be adapted for use in the present invention. One example of such a printer is the ModelMaker II™ printer available from Solidscape, Inc. (formerly "Sanders-Prototype, Inc."). The

Col. 6:

In the illustrated embodiment, the deposition portion **133** includes a housing **137** into which a fluid flows. To facilitate deposition accuracy, the housing **137** may have a conical shape so the diameter of the housing **137** is about 4 millimeters at the top portion and about 2 millimeters at the bottom portion. From the housing **137**, the fluid then flows to a hollow needle or tube **139**. The size of the needle **139** depends on the type of fluid, the substrate, the printing pattern, and other factors. However, it is generally desired that the needle **139** is large enough to allow any particulates to pass therethrough without substantial sticking or clogging, but small enough to provide the desired deposition accuracy. For example, in one embodiment the needle **139** is a 30-gauge needle that allows cells up to about 100 micrometers in diameter to pass therethrough without substantial sticking or clogging. Of course, smaller and larger needles **139** are also contemplated in the present invention. For instance, in some embodiments, cells having diameters of up to several hundred micrometers (e.g., cell aggregates) may be printed in accordance with the present invention.

Col. 15:

Regardless of the pattern and/or density selected, the present invention may utilize various control techniques to ensure that the desired results are achieved. Unlike conventional techniques for printing cells that involve contact-deposition, the present invention provides a precise, well-controlled method of printing that does not substantially risk contamination. The non-contact, ink-jet printing techniques employed in the present invention also allow for better control than previously realized when depositing viable cells onto a substrate. Generally speaking, any well-known ink-jet printing control technique may be utilized in the present invention. For instance, a printer driver may be used to control the movement of the printer head, the movement of the substrate, the voltage delivery to the printer head, etc. Some suitable ink-jet printing control techniques that may be adapted for use in the present invention are described in

Referring to FIG. 8, for instance, a block diagram of one embodiment of a control system that may be used in the present invention is shown. As shown, the system includes a host computer 500 and an ink-jet printer 100 (FIG. 1). In the host computer 500, the exchange of various data and control are generally performed between an OS (Operating System) 501 and application software 502 that operates on the OS 501. Print data is exchanged between the OS 501, the application software 502, and a printer driver 503, and is sent to the printer 110 through the printer driver 503. The present invention is by no means limited to any particular printer driver because, as is well known to those skilled in the art, numerous types of printer drivers may accomplish the same functions desired in the present invention.

The flow of data in the process of printing out cell composition(s) from the printer **100** is generally described below. Typically, a user first inputs the desired cell density and pattern into the application software **502**. These data signals are then sent to the printer driver **503**. The printer driver **503** performs processing for the received signals, and also generally converts them into binary signals. The printer driver **503** sends these signals to the interface, in the host computer **500**, which is used for the printer **100** or the interface for a file storage unit or the like. The signals are then sent as output to the interface for the printer **100**, and the data signals are sent to controller software **601** in the printer **100**. Matching between the set print mode and a printer head **110** is checked. Thereafter, the print data is transferred to engine software **602**. In this case, the engine software **602** interprets the received data as data indicating the print mode and the data structure designated by the controller software **601**, converts the print data into discharge pulses, and sends them to the printer head **110**. With this operation, cell composition(s) are discharged from the printer head **110**. The ID information of the printer head **110**, the ID information of each cell composition reservoir, etc., are sent to the engine software **602**. On the basis of these

Col. 17:

A modified Canon® Bubble Jet 2100 printer was used to print the bacteria cells onto the coverslip substrate. The Canon® printer was modified by removing the rubber rolls and removing the center springs, and tightening the remaining springs designed to advance paper.

Microsoft PowerPoint software was used to edit a linear colony array pattern with a 2 drops per millimeter density and 0.13 pt weight (Microsoft® PowerPoint™). A black ink-jet cartridge was emptied of its contents, thoroughly cleaned with a 100% ethanol solution, rinsed using auto-claved water, and dried in a sterilized hood. Thereafter, the cartridge was filled with 1 milliliter of a bacterial printing suspension.

A modified HP® DeskJet 550C printer was used to print the bacteria cells onto the microscope slide substrate. The HP® printer was modified with gear mount pillars having closer tolerances, which was accomplished by adding a horizontal support, changing the transistor in the circuit to one with higher amplification, and re-entering the horizontal position encoder. Both printers utilized a printer driver to allow different viscosities of solutions to be printed. The printer drivers constantly adjusted the voltages to the nozzles to account for different impedances of the solutions, thus allowing the appropriate amount of solution to be dispensed. The printer drivers are available for download at the following website: http://130.127.152.24.

2. The process of claim 1 further comprising using Boolean, scaling, smoothing, mirroring, to modify the CAD design prior to conversion into a heterogeneous material and multi-part assembly model.

Col. 14:

Using the techniques described above, it has been discovered that cells may be printed onto a substrate and remain viable. However, not only does the present invention provide a mechanism for ensuring cell survival, it also provides the ability to easily, quickly, and inexpensively manipulate the types of patterns, densities, etc., that may be printed. For instance, the printed patterns may be simple or complex, and have a shape that is regular or irregular. In fact, due to the control provided by the present invention, there is essentially no limit on the patterns or shapes capable of being printed according to the present invention.

Col. 15:

Referring to FIG. 8, for instance, a block diagram of one embodiment of a control system that may be used in the present invention is shown. As shown, the system includes a host computer 500 and an ink-jet printer 100 (FIG. 1). In the host computer 500, the exchange of various data and control are generally performed between an OS (Operating System) 501 and application software 502 that operates on the OS 501. Print data is exchanged between the OS 501, the application software 502, and a printer driver 503, and is sent to the printer 110 through the printer driver 503. The present invention is by no means limited to any particular printer driver because, as is well known to those skilled in the art, numerous types of printer drivers may accomplish the same functions desired in the present invention.

3. The process of claim 1 wherein in step (a) data taken from MRI, CT or other patient specific data is imported into the CAD environment to design the part or device to be created. Col. 16:

The techniques for printing viable cells in accordance with the present invention may be employed in a wide variety of applications. One such application is the formation of genomic and protein expression libraries. For instance, these libraries typically require high throughput screening of thousands of bacteria cells to identify specific DNA sequences, investigate gene expression, and/or search for differentially expressed genes. Patterns of bacteria cells may also be printed according to the present invention to build biosensors, such as to monitor environmental components and detect toxicological contamination. In addition, artificial chromosome libraries and other cell-based sensors may also be formed. The present invention may also be employed in tissue engineering and even organ production.

4. The process of claim 1 wherein a biomimetic and non-biomimetic feature is designed into the part or device.

(Note that plainly stated biomimetics refers to human-made processes, substances, devices, or systems that imitate nature (mimetic: Late Latin *mimeticus*, from Greek *mimētikos*, from *mimeisthai* to imitate, from *mimos* mime; from Gk. *Bio-*, comb. form of *bios* "life, course or way of living"). The non-biomimetic scaffold is used to grow the biomemtic (cells/organ) portion.)

In this context, see col. 10:

Besides gels, other support compounds may also be utilized in the present invention. Extracellular matrix analogs, for example, may be combined with support gels to optimize or functionalize the gel. One or more growth

The manner in which the support compound and/or cells may be deposited onto a substrate may generally vary. For instance, FIG. **4** is a schematic illustration of one embodiment in which layers are deposited onto a substrate **216** using the printer **100** of FIG. **1**. Initially, the substrate **216** is supplied at an end **211** of the feed mechanism **114** (FIG. **1**). The wheels **135** of the feed mechanism **114** rotate clockwise, so that the substrate **216** is moved closer to the printer head **110**. After reaching the desired position, the wheels **135** stop so that the printer head **110** is positioned to deposit the fluids at the desired location. In this embodiment, three fluids (the same or different) are supplied from reservoir(s) (not shown) to nozzles **210**, **212**, and **214** of the printer head **110**. The printer head **110** may make multiple passes over the substrate **216**. For instance, in one embodiment, the printer head **110** moves back and forth in the **-x** direction to make multiple passes over the substrate **216** as it rests on the feed

5. The process of claim 1 wherein the part or device comprises a tissue engineering device and printing in step (c) involves direct deposition of cells or biological factors.

(intended use for the process. These are process claims, not product-by-process claims. No patentable weight provided; limitation "d" is not considered in view of the ambiguity and Applicant's silence on this issue. Regardless, Boland teaches both direct and non-direct contact. See title: "Ink-jet printing of viable cells"). Col. 17:

A modified HP® DeskJet 550C printer was used to print the bacteria cells onto the microscope slide substrate. The HP® printer was modified with gear mount pillars having closer tolerances, which was accomplished by adding a horizontal support, changing the transistor in the circuit to one with higher amplification, and re-entering the horizontal position encoder. Both printers utilized a printer driver to allow different viscosities of solutions to be printed. The printer drivers constantly adjusted the voltages to the nozzles to account for different impedances of the solutions, thus allowing the appropriate amount of solution to be dispensed. The printer drivers are available for download at the following website: http://130.127.152.24.

Col. 16:

The techniques for printing viable cells in accordance with the present invention may be employed in a wide variety of applications. One such application is the formation of genomic and protein expression libraries. For instance, these libraries typically require high throughput screening of thousands of bacteria cells to identify specific DNA sequences, investigate gene expression, and/or search for differentially expressed genes. Patterns of bacteria cells may also be printed according to the present invention to build biosensors, such as to monitor environmental components and detect toxicological contamination. In addition, artificial chromosome libraries and other cell-based sensors may also be formed. The present invention may also be employed in tissue engineering and even organ production.

Col. 17:

A modified Canon® Bubble Jet 2100 printer was used to print the bacteria cells onto the coverslip substrate. The Canon® printer was modified by removing the rubber rolls and removing the center springs, and tightening the remaining springs designed to advance paper.

Boland also discloses that direct contact was standard in the art, and that non-direct has certain advantages: Col. 15:

Regardless of the pattern and/or density selected, the present invention may utilize various control techniques to ensure that the desired results are achieved. Unlike conventional techniques for printing cells that involve contact-deposition, the present invention provides a precise, well-controlled method of printing that does not substantially risk contamination. The non-contact, ink-jet printing techniques employed in the present invention also allow for better control than previously realized when depositing viable cells onto a substrate. Generally speaking, any well-known ink-jet printing control technique may be utilized in the present invention. For instance, a printer driver may be used to control the movement of the printer head, the movement of the substrate, the voltage delivery to the printer head, etc. Some suitable ink-jet printing control techniques that may be adapted for use in the present invention are described in

6. The process of claim 5 wherein direct cell deposition improves histological accuracy, cell ratios, and spatial patterning of cells in the part or device.

(The limitation is directed to a subjective test and furthermore refers to an intended purpose. However, the consequence appears to be an inherent result of the cause - the direct deposition)

7. The process of claim 1 wherein the part or device produced comprises an artificial organ, a tissue scaffold, an artificial vasculature or channel system, or a sample for cytotoxicity testing.

(intended use for the process. These are process claims, not product-by-process claims. No patentable weight provided).

8. The process of claim 1 wherein the part or device produced comprises a biochip, biosensor, bionic, cybernetic, mechanoactive, or a bioactive tissue scaffold.

(intended use for the process. These are process claims, not product-by-process claims. No patentable weight provided).

9. The process of claim 1 wherein the part or device is **used** in drug delivery.

(Intended use - no patentable weight provided. The claims are directed to a process for manufacturing complex parts and devices.

10. A multi-nozzle biopolymer deposition apparatus comprising:

(a) a data processing system which processes a designed scaffold model and converts it into a layered process tool path;

(see limitations a, b, of claim 1)

(b) a motion control system driven by the layered process tool path:

(see limitations a, b, of claim 1)

(c) a material delivery system comprising multiple nozzles of different types and sizes for *simultaneously depositing specified hydrogels with different viscosities thereby constructing a scaffold from the designed scaffold model.*

("***for simultaneously depositing specified hydrogels with different viscosities***" *refers to intended use* – no patentable weight. The claims are directed to a multi-nozzle biopolymer deposition apparatus."***thereby constructing a scaffold from the designed scaffold model***" also refers to intended use and is therefore provided no patentable weight.)

See fig. 2:

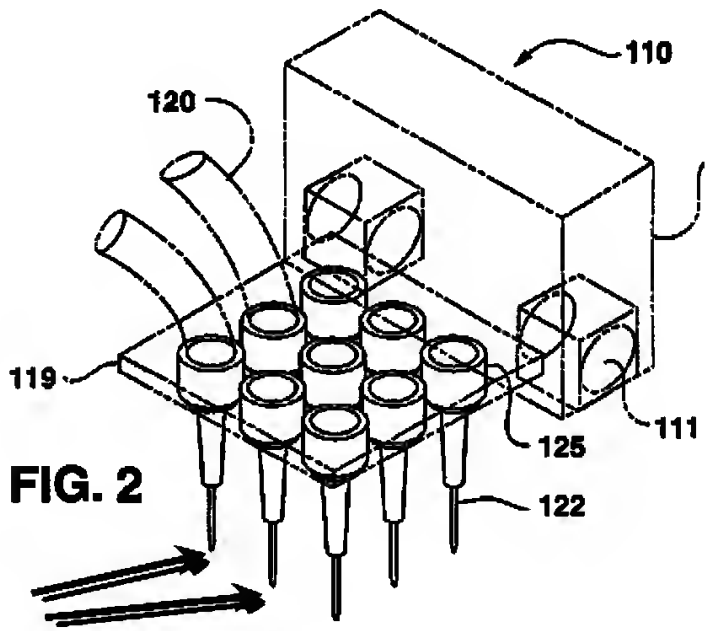


FIG. 2

Regardless, see Col. 17:

position encoder. Both printers utilized a printer driver to allow different viscosities of solutions to be printed. The printer drivers constantly adjusted the voltages to the nozzles to account for different impedances of the solutions, thus allowing the appropriate amount of solution to be dispensed. The printer drivers are available for download at the following website: http://130.127.152.24.

As for scaffolds, see col. 10:

Besides gels, other support compounds may also be utilized in the present invention. Extracellular matrix analogs, for example, may be combined with support gels to optimize or functionalize the gel. One or more growth

The manner in which the support compound and/or cells may be deposited onto a substrate may generally vary. For instance, FIG. **4** is a schematic illustration of one embodiment in which layers are deposited onto a substrate **216** using the printer **100** of FIG. **1**. Initially, the substrate **216** is supplied at an end **211** of the feed mechanism **114** (FIG. **1**). The wheels **135** of the feed mechanism **114** rotate clockwise, so that the substrate **216** is moved closer to the printer head **110**. After reaching the desired position, the wheels **135** stop so that the printer head **110** is positioned to deposit the fluids at the desired location. In this embodiment, three fluids (the same or different) are supplied from reservoir(s) (not shown) to nozzles **210**, **212**, and **214** of the printer head **110**. The printer head **110** may make multiple passes over the substrate **216**. For instance, in one embodiment, the printer head **110** moves back and forth in the −x direction to make multiple passes over the substrate **216** as it rests on the feed

Response to Arguments

10. Applicant's arguments, filed 8/28/2009, have been carefully considered and are not persuasive.

11. Applicants object (pg. 5) to the Examiner's interpretation of the word 'simultaneously', but do not put forth what they believe to be a correct interpretation:

> In the previous response, Applicants argued that the "word "simultaneous" is defined as "existing or occurring at the same time." (see simultaneous. (2009).In Merriam- Webster Online Dictionary. Retrieved March 5, 2009, from www.merriam-webster.com/ dictionary/simultaneous. The word simultaneous is not used inconsistently with this definition in the specification. Nothing in this definition, or in the use of the term simultaneous, addresses any spatial relationship, as Examiner has asserted it might. The Examiner has not cited any reference or text to support the contention that the term simultaneous in any context says anything at all about any spatial relationship."

The issue is that the claims are directed to simultaneous deposition by more than one nozzle. How can two nozzles be dispensing at the same location at the same time? Claim 10 is directed to simultaneously depositing at different locations at the same exact time. Applicants have not clarified the issue, and only provide allegation. The interpretation will be maintained until such clarification is provided.

12. The 112-2 rejections against claims 2, 5, are withdrawn in view of the amendment.

13. Applicants argue (pg. 6):

> Specifically, the Examiner asserts that claim 3 is indefinite for not setting forth any steps involved in the process. Applicants respectfully submit that claim 3 depends from claim 1. Claim 1 sets forth at least 3 steps involved in the process. "Claims in dependent form shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim." MPEP 608.01 (i). Therefore, claim 3 sets forth all the steps in the process

> as set forth in claim 1. Applicants note that the Examiner has not rejected claim 1 for being indefinite.

Applicants have not addressed the issue and instead refer to claim 1. *Claim 3* provides for the use of *patient specific data*, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

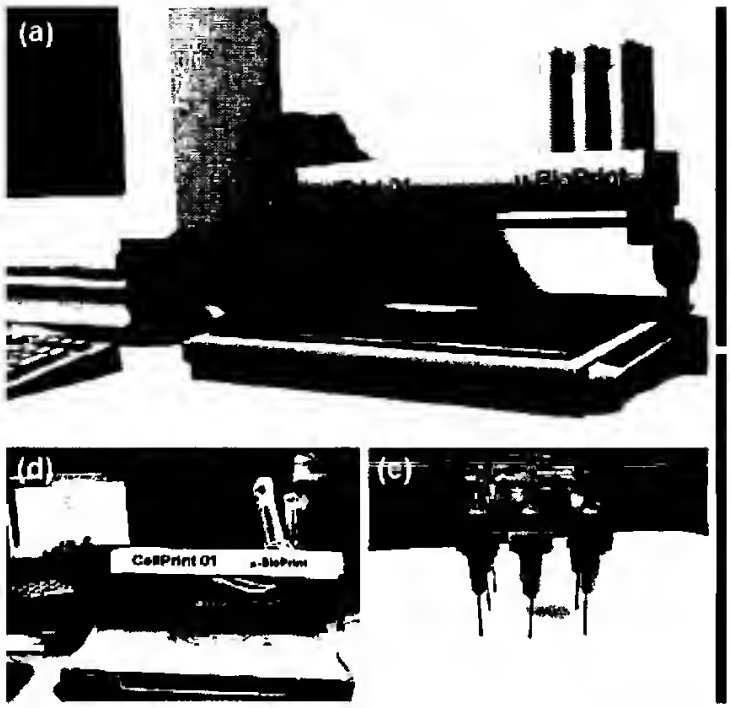
14. The *131* affidavit (8/26/2009) is not persuasive. To the extent that it is directed to the withdrawn Mironov publication, it is not relevant. Regarding the patent (see par. 10-11 of the affidavit), Applicants have not established a 'date of invention' of 2/22/2003. Applicants have only established (as per the criterion applicable to 1.132 affidavits) that they provided a drawing of a multi-nozzle printer to Mironov at that time.

15. In this respect, clarification is requested. The affidavit (8/28/2009) states that the figure in question (that was provided to Mironov) was:

Exhibit B

Exhibit C

However, the figure in Mironov is:



16. Furthermore, it appears that Applicants are now attempting to 'swear back' the date of their invention with a 1.131 affidavit (the previous *1.132* affidavit of 3/5/2009 was used to establish that figure 2a of Mironov was Applicant's own work, thus invalidating the 102(a) rejection). That is not the same as establishing proof of conception of the claimed invention which is directed to more than just a multi-nozzle printer.

17. It is unclear whether Applicants are alleging actual or constructive reduction to practice, and if actual reduction, whether it occurred prior to or subsequent to the effective date of the reference. See MPEP 715.07 III: **THREE WAYS TO SHOW PRIOR INVENTION**):

> (A) actual reduction to practice of the invention prior to the effective date of the reference; or

(B) conception of the invention prior to the effective date of the reference coupled with due diligence from prior to the reference date to a subsequent (actual) reduction to practice; or

(C) conception of the invention prior to the effective date of the reference coupled with due diligence from prior to the reference date to the filing date of the application (constructive reduction to practice).

18. Applicants have not established or even discussed reduction to practice (MPEP 715.07 III), conception (as per the criteria established in MPEP 715.07 III), nor diligence (MPEP 715.07 (a)).

19. Applicants have made no other arguments against the applied art.

20. Applicants argue (pg. 8):

> Moreover, applicants do not understand the timing of the Examiner's newly raised 102(e) rejection. In the Office Action dated September 8, 2008, the § 102(a) rejection based on Mironov was overcome and withdrawn by the Examiner in light of the previously submitted Declaration which established a date of invention prior to February 22, 2003. Thus, the present Office Action citing new art that is dated later than February 22, 2003 is repugnant to the principles of compact prosecution set for in MPEP §2106.

21. The applied reference was not before the office at that time. Furthermore, the 102(e) rejection is not cumulative to the 102(a) rejection.

22. Applicants have not established a 'date of invention' of 2/22/2003. Applicants have only established that they provided a drawing of a multi-nozzle printer to Mironov at that time. It is noted that it is not possible to determine the brand of the printer from Applicant's fig. 2 (priority document, 6/29/2005).

23. In any case, Boland discloses that many different types of printers can be used, including Canon and HP models, as noted in the rejection of claim 1.

Col. 4:

Generally speaking, any known ink-jet printer and/or ink-jet printing system may be incorporated for use in the present invention. Ink-jet printers are typically either "DOD" (Drop-On-Demand) or "continuous" ink-jet printers. In a continuous ink-jet printer, a stream of fluid con-

In addition, various ink-jet printers used to print layers on plastic parts (known as "rapid prototyping") may also be adapted for use in the present invention. One example of such a printer is the ModelMaker II™ printer available from Solidscape, Inc. (formerly "Sanders-Prototype, Inc."). The

Col. 17:

A modified HP® DeskJet 550C printer was used to print the bacteria cells onto the microscope slide substrate. The HP® printer was modified with gear mount pillars having closer tolerances, which was accomplished by adding a horizontal support, changing the transistor in the circuit to one with higher amplification, and re-entering the horizontal position encoder. Both printers utilized a printer driver to allow different viscosities of solutions to be printed. The printer drivers constantly adjusted the voltages to the nozzles to account for different impedances of the solutions, thus allowing the appropriate amount of solution to be dispensed. The printer drivers are available for download at the following website: http://130.127.152.24.

Col. 17:

> A modified Canon® Bubble Jet 2100 printer was used to print the bacteria cells onto the coverslip substrate. The Canon® printer was modified by removing the rubber rolls and removing the center springs, and tightening the remaining springs designed to advance paper. 35

24. Regarding 'compact prosecution', Applicants are respectfully reminded that the Examiner attempted to assist Applicants by providing substantial suggestions over two years ago.

Conclusion

25. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Landers et al. (of record; IDS of 10/26/2007) discloses:

> **Desktop manufacturing of complex objects, prototypes and biomedical scaffolds by means of computer-assisted design combined with computer-guided 3D plotting of polymers and reactive oligomers**
>
> *Rüdiger Landers Rolf Mülhaupt**

26. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period